510(k) Summary

FEB 2 6 2014

In accordance with 21 CFR 807.92(c) the following summary of information is provided:

Date Prepared: November 22, 2013

Submitter:
eZono AG
Spitzweidenweg 30
Jena, GERMANY D-07743

Contact Person:
Graham Cox
CEO
eZono AG
Spitzweidenweg 30
Jena, GERMANY D-07743

Telephone: 425.408.0743

FR Numbers/Product Codes:
892.1550/IYN, Ultrasonic Pulsed Doppler Imaging System
892.1560/IYO, Ultrasonic Pulsed Echo Imaging System
892.1570/ITX, Diagnostic Ultrasound Transducer

Common Name: Diagnostic Ultrasound System with Accessories

Trade Name: eZono™ 4000 Ultrasound System

Regulatory Class: Class II

Classification Panel: Radiology

Predicate Device(s):
eZono™ 3000 Series Ultrasound System (K120234)
Terason t3000 Ultrasound Systems With Updated Needle Guidance Graphics (K112953)
Ultrasonix Sonixgps Needle Sensor (K111818)
SonoSite M-Turbo (K130173)

Intended Use/ Indications For Use:
Diagnostic ultrasound imaging or fluid flow analysis of the human body.
The indications for use of the eZono™ 4000, as defined by FDA guidance documents, are:

Fetal	Invasive diagnostic or therapeutic
Abdominal	Retroperitoneum
Pediatric	Female reproductive system and
Small Organ (breast, thyroid,	Superficial structures & pathologies
Musculo-skeletal	Peripheral Vessel
Musculo-skeletal (Superficial)	Magnetic Needle guidance

Device Description: The eZono 4000 system is a portable, software-controlled sonography system based on a digital architecture. It supports linear and curvi-linear transducers. The eZono 4000 system has an ergonomic design optimized for stable handling without sharp edges and is very easy to carry with its low weight of 11.5lbs (5.2kg). The robust casing provided with an anti-slip bottom side. The brilliant 12-inch screen with more than 60 million colors makes it possible to acquire and display high-resolution, real-time ultrasound images. The eZono Needle Guide System detects the position and orientation of magnetized needles in the presence of the probe and displays this information relative to the ultrasound image. This guides the operator to better visualize the needle in the ultrasound image during ultrasound guided needling procedures.

Device Modifications: The eZono 4000™ Ultrasound System has similar construction, manufacturing materials, operating principals and specifications as the predicate device. The eZono 4000 Ultrasound System magnetic needle guidance system has similar operating principals and specifications as the predicate device.

The differences between the eZono 4000 Ultrasound System and the predicate eZono 3000 Ultrasound System include the following:

1. Added the clinical application "magnetic needle guidance" to the system.
2. Add supported transducer: L3-12NGS, L3-12 and CL1-6.
3. Introduced the trade name of eZono 4000 and eZGuide for the ultrasound system and needle guidance system respectively.
4. Add the following supported accessories:
5. eZono 4000 Sterile Needle Magnetizer with trade name "eZMag".

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The eZono 4000 System has been found to conform to the system specifications, thermal, electrical, electromagnetic and mechanical safety, and to FDA consensus, medical device safety standards, and international harmonized standards. The eZono 4000 System and its applications comply with the following standards:

1. AAMI HE75:2009 Human factors engineering - Design of medical devices
2. IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
3. IEC 60601-1-2 Medical Electrical Equipment, Part 1: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
4. IEC 60601-2-37 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
5. IEC 62304 Medical device software - Software life cycle processes
6. IEC 62366 Medical devices - Application of usability engineering to medical devices
7. ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing
8. ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
9. ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity
10. ISO 14971 Medical devices – application of risk management to medical devices

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Non-Clinical Tests:

The subject of this premarket submission, eZono 4000 System, did not require clinical studies to support substantial equivalence.

Substantial Equivalence:

The modified eZono 4000 System has similar construction, manufacturing materials, operating principals and specifications as the predicate devices. Therefore, eZono AG considers the modified eZono 4000 System substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 26, 2014

eZono AG
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K140254
Trade/Device Name: eZono™ 4000
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: February 4, 2014
Received: February 5, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the eZono™ 4000, as described in your premarket notification:

Transducer Model Number

L3-12NGS	CL1-6	L3-12

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140254

Device Name
eZono™ 4000

Indications for Use *(Describe)*

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Indications For Use:

The indications for use of the eZono™ 4000, as defined by FDA guidance documents, are:

Fetal, Abdominal, Pediatric, Small Organ (breast, thyroid, testicle), Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Invasive diagnostic or therapeutic procedures, Retroperitoneum, Female reproductive system and fetus. Superficial structures & pathologies, Peripheral Vessel, Magnetic Needle guidance

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Table 1.3- 1 Indications for Use Form – eZono 4000 System

System:	eZono™ 4000
Transducer:	Currently Supported[1]
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler (CD)	Combined (B+CD)	Other* (Color Power Doppler)
Ophthalmic	Ophthalmic							
	Fetal	P	P			P	P	P
	Abdominal	P	P			P	P	P
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	P	P			P	P	P
	Small Organ (breast, thyroid, testicles)	P	P			P	P	P
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P			P	P	P
	Musculo-skel. (Superfic.)	P	P			P	P	P
	Intravascular							
	Invasive diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access, magnetic needle guidance)	N	N			N	N	N
	Retroperitoneum	P	P			P	P	P
	Female reproductive system & Fetus (transcutaneous)	P	P			P	P	P
	Superficial structures & pathologies	P	P			P	P	P
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Intra-cardiac							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P			P	P	P
Vessel	Magnetic needle guidance	N	N			N	N	N

Prescription Use (Per 21 CFR 801.109)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

1. Supported transducer models are L3-12NGS, CL1-6, and L3-12. See their corresponding IFU tables.

All items marked "P" were previously cleared in 510(k) K120234

Table 1.3- 2 Indications for Use Form – eZono 4000, L3-12NGS Transducer

System:	eZono™ 4000
Transducer:	L3-12NGS
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	**Specific (Tracks I & III)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler (CD)**	**Combined (B+CD)**	**Other* (Color Power Doppler)**
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	N	N			N	N	N
	Small Organ (breast, thyroid, testicles)	N	N			N	N	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	N	N			N	N	N
	Musculo-skel. (Superfic.)	N	N			N	N	N
	Intravascular							
	Invasive diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access, magnetic needle guidance)	N	N			N	N	N
	Retroperitoneum							
	Female reproductive system & Fetus							
	Superficial structures & pathologies (Incl. lungs)	N	N			N	N	N
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Intra-cardiac							
	Other (spec.)							
Peripheral	Peripheral vessel	N	N			N	N	N
Vessel	Magnetic needle guidance	N	N			N	N	N

Prescription Use (Per 21 CFR 801.109)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

All items marked "P" were previously cleared in 510(k) K120234

Table 1.3- 3 Indications for Use Form – eZono 4000, CL1-6 Transducer

System:	eZono™ 4000
Transducer:	CL1-6
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	**Specific (Tracks I & III)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler (CD)**	**Combined (B+CD)**	**Other* (Color Power Doppler)**
Ophthalmic	Ophthalmic							
	Fetal	N	N			N	N	N
	Abdominal	N	N			N	N	N
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	N	N			N	N	N
	Small Organ (breast, thyroid, testicles)							
	Neonatal Cephalic	N	N			N	N	N
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	N	N			N	N	N
	Musculo-skel. (Superfic.)	N	N			N	N	N
	Intravascular							
	Invasive diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access)	N	N			N	N	N
	Retroperitoneum	N	N			N	N	N
	Female reproductive system & Fetus	N	N			N	N	N
	Superficial structures & pathologies (Incl. lungs)	N	N			N	N	N
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Intra-cardiac							
	Other (spec.)							
Peripheral	Peripheral vessel	N	N			N	N	N
Vessel	Magnetic needle guidance							

Prescription Use (Per 21 CFR 801.109)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

All items marked "P" were previously cleared in 510(k) K120234

Table 1.3- 4 Indications for Use Form – eZono 4000, L3-12 Transducer

System:	eZono™ 4000
Transducer:	L3-12
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler (CD)	Combined (B+CD)	Other* (Color Power Doppler)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	N	N			N	N	N
	Small Organ (breast, thyroid, testicles)	N	N			N	N	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	N	N			N	N	N
	Musculo-skel. (Superfic.)	N	N			N	N	N
	Intravascular							
	Invasive diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access)	N	N			N	N	N
	Retroperitoneum							
	Female reproductive system & Fetus							
	Superficial structures & pathologies (Incl. lungs)	N	N			N	N	N
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Intra-cardiac							
	Other (spec.)							
Peripheral	Peripheral vessel	N	N			N	N	N
Vessel	Magnetic needle guidance							

Prescription Use (Per 21 CFR 801.109)
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

All items marked "P" were previously cleared in 510(k) K120234